K030455

510(k) Summary of Safety and Effectiveness

MAR 1 3 2003

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Lynn Harmer
Manager Regulatory Submissions
Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431
Telephone: (425) 487-7312
Facsimile: (425) 487-8666
E-mail: Lynn.Harmer@Philips.com

Date prepared: 16 January 2003

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic ultrasound system with accessories
Proprietary Name: Boris Platform Diagnostic Ultrasound System

Classification Name	Federal Regulations Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasonic Transducer	892.1570	90-ITX

3) Substantially Equivalent Devices

Philips Ultrasound believes that the Boris Platform system and transducers are substantially equivalent to the currently marketed Philips HDI® 5000 ultrasound system and transducers cleared in K961459, K991671, and K002003.

3) Device Description

The Boris system is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation.

The device consists of two parts: the system console and the transducer. The system console contains the user interface, a display, system electronics and optional peripherals (printers, VCR). In addition to the physical knobs and buttons of the main control panel,

the user interface consists of a Touch Panel, to access additional less-frequently-used controls, and the Alphanumeric Keyboard to enter patient data and other text.

The removable transducers are connected to the system using standard technology. The Boris system uses standard transducer technology, and supports phased, linear, and curved linear arrays, TEE, motorized 3D curved linear arrays as well as Non-Imaging (Pencil) probes.

The Boris system gives the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

Clinical data storage consists of a local repository as well as off-line image storage via the network or DVD. The images are stored in industry-standard formats (Ex: JPEG, AVI, DICOM) and are intended to be readable using industry-standard hardware and software. On-line review of the images is available. Secure access tools are provided to restrict and log access to the clinical data repository according to HIPAA.

The Boris Platform system has been designed to meet the following standards:

- IEC 60601-1
- UL 2601-1
- C22.2 No. 601.1
- IEC 60601-1-2
- IEC 60601-2-37
- NEMA UD 2 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.
- NEMA UD 3 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

4) Intended Use

The Boris Platform system and transducers are intended for diagnostic ultrasound imaging and fluid flow analysis of the human body. The clinical applications include: ophthalmic, fetal, abdominal, intra-operative, laparoscopic, pediatric, small organ, neonatal/adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal, cardiac, trans-esophageal, peripheral vessel and cerebral vascular applications.

Typical examinations using the Boris Platform system include:

- General abdominal and pelvic studies including organ surveys, blood flow assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and testicles.
- Pediatric scans of organs, superficial, and bony structures.
- Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.
- Monitoring procedures for infertility studies (other than in vitro fertilization.)

- First, second, and third trimester pregnancy studies.
- Prostate, prostate biopsy guidance, and rectal wall studies.
- Neonatal head studies.
- Transcranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.
- Cardiac studies in adults and children.
- Monitoring of cardiac function during procedures using transesophageal echocardiography.
- Biopsy guidance for tissue or fluid sampling.
- Assessment of cardiac muscle, coronary arteries and great vessels during cardiac surgery.
- Study of myocardial function in adults
- Study of eye anatomy including blood flow in retinal vessels and branches.
- Study of esophagus, stomach, biliary system, pancreas and gastrointestinal tract using endoscopic probe.
- Study of abdominal and pelvic organs and masses using laparoscopic probe.
- Examination of organs, masses and vessels during surgical procedures.
- Study of muscles, ligaments, nerve bundles and connective tissue.

5) Technical Characteristics

This device operates identically to the predicate device in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode images. Doppler shift caused by blood flow or tissue is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, M-mode, Color Doppler, Color M-Mode, Color Power Angio, CW Doppler, Tissue Doppler Imaging, Pulsed Tissue Doppler, and Pulsed Doppler) are the same as the predicate device.

6) Conclusion

The Boris Platform ultrasound system and transducers are substantially equivalent in safety and effectiveness to the HDI 5000 system and transducers.

- Both systems are intended for diagnostic ultrasound imaging and fluid flow analysis.
- Both systems use essentially the same technologies for imaging, Doppler functions and signal processing.
- Both systems have acoustic output levels below the applicable FDA limits.
- Both systems are manufactured of materials with materials that have been evaluated and found to be safe for its application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2003

Philips Ultrasound, Inc.
% Ms. Laura Danielson
510(k) Program Manager
TUV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K030455
Trade Name: Boris Platform Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: February 28, 2003
Received: March 3, 2003

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Boris Platform Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2 / 5.0-2.0 MHz / 40mm Curved Array
C8-4v / 8.0-4.0 MHz / 11mm / Curved Array
C8-5 / 8.0-5.0 MHz / 14mm Curved Array

C9-4 / 4.0-9.0 MHz / 40mm Curved Array
C9-5ec / 9.0-5.0 MHz / 8mm / Curved Array
D2 CW / 2.0 MHz / Static Probe
D2 TC / 2.25 MHz / Static Probe
L8-4 / 8.0-4.0 MHz / 38mm / Linear Array
L9-5 –LAP / 9.0-5.0 MHz / 28mm / Laparascopic Linear Array
L12-5 / 12.0-5.0 MHz / 50mm / Linear Array
L15-7 i.o. / 15-7.0 MHz / 38mm / Linear Array
L17-5 / 5.0-17.0 MHz / 39mm Linear Array
S3-1 / 1.0-3.0 MHz / Phased Array
S4-1 / 4.0-1.0 MHz / Phased Array
S6-2t Trans-Esophageal (Adult) 2.0-6.0 MHz / 9mm / motorized phased
x-Matrix Multi-Dimensional Phased Array
3D IVT / 7.5 MHz / 11.5mm Motorized Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer:
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	N	N	N		N	Notes 1, 3	Notes 5, 6, 8,10,12, 13
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 7, 8, 10, 12, 13
	Abdominal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 7, 8, 10, 11, 12, 13
	Intra-operative *(Abdominal, Spine, Vascular)*	N	N	N		N	Notes 1, 3	Notes 5, 6, 8,10,12, 13
	Intra-operative (Neuro.)	N	N	N		N	Notes 1, 3	Notes 3, 5, 6, 10, 12, 13
	Laparoscopic	N	N	N		N	Notes 1, 3	Notes 8, 10, 12, 13
	Pediatric	N	N	N		N	Notes 1, 2, 3	Note 5, 6, 8, 9, 10, 12, 13
	Small Organ *(breast, thyroid, testicle)*	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 11, 12, 13
	Neonatal Cephalic	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Adult Cephalic	N	N	N	N	N	Notes 1, 3, 4	Notes 10, 13
	Trans-rectal	N	N	N		N	Notes 1, 3	Notes 5, 6, 10, 12, 13
	Trans-vaginal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 10, 12,
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8,10, 12,13
	Musculo-skel. (Superficial)	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12,13
	Intra-luminal							
	Other: Urology	N	N	N		N	Notes 1, 3	Notes 5, 10, 12
Cardiac	Cardiac Adult	N	N	N	N	N	Notes 1,2,3,4	Notes 10, 13
	Cardiac Pediatric	N	N	N	N	N	Notes 1,2,3,4	Notes 10, 11, 13
	Trans-esophageal (Cardiac)	N	N	N	N	N	Notes 1,2,3,4	Note 10
	Other *(Fetal Echo)*	N	N	N	N	N	Notes 1,2,3,4	Notes 10, 12, 13
Peripheral Vessel	Peripheral vessel	N	N	N		N	Notes 1, 2, 3	Notes 2, 3, 5, 6, 7, 8, 10, 12, 13
	Cerebral Vascular	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **C5-2 / 5.0 – 2.0 MHz / 40mm Curved Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 7, 8, 10, 12
	Abdominal	N	N	N		N	Notes 1, 3	Notes 5, 6, 8. 10, 12
	Intra-operative *(Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 9, 10, 12
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Notes 2, 3, 5, 7
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **C8-4v / 8.0-4.0 MHz / 11mm / Curved Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 3	Notes 5, 6, 10, 12
	Abdominal	N	N	N		N	Notes 1, 2, 3	Notes 5,6,7,10,12
	Intra-operative *(Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 10, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Urology	N	N	N		N	Notes 1, 3	Notes 5, 10, 12
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **C8-5 / 8.0-5.0 MHz / 14mm Curved Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Abdominal	N	N	N		N	Notes 1, 3	Notes 5, 7, 8, 10 12, 13
	Intra-operative *(Abdominal, vascular)*							
	Intra-operative (Neuro.)	N	N	N		N	Notes 1, 3	Notes 3, 5, 6, 10, 12, 13
	Laparoscopic							
	Pediatric	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Small Organ							
	Neonatal Cephalic	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (*Specify*)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Notes 1, 3,	Notes 5, 8, 10, 12
	Cerebral Vascular	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **C9-4/4.0-9.0 MHz/ 40 mm Curved Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Abdominal	N	N	N		N	Notes 1, 3	Notes 5, 6, 7, 8, 10, 12, 13
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **C9-5ec / 9.0-5.0 MHz / 8mm / Curved Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	*Fetal*	N	N	N		N	Notes 1, 3	Notes 5, 10, 12,
	Abdominal							
	Intra-operative *(Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Notes 1, 3	Notes 5, 6, 10, 12, 13
	Trans-vaginal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 10, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	*Peripheral vessel*							
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **D2 CW / 2.0 MHz / Static Probe**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC UTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **D2 TC / 2.25MHz Static Probe**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **L8-4 / 8.0-4.0 MHz / 38mm / Linear Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Intra-operative (Specify)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Small Organ (Breast)	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 11, 12, 13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13
	Musculo-skel. (Superficial)	N	N	N		N	Notes1, 2, 3	Notes 5, 6, 8, 10, 12, 13
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13
	Cerebral Vascular	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **L9-5 -LAP / 9.0 – 5.0 MHz / 28mm / Laparascopic Linear Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (abdomen)	N	N	N		N	Notes 1, 3	Notes 8, 10, 12, 13
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N		N	Notes 1, 3	Notes 8, 10, 12, 13
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel							
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and **Radiological Devices**
510(k) **Number** K130455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **L12-5 / 12.0 – 5.0 MHz / 50mm / Linear Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13
	Abdominal	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 11, 12, 13
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13
	Small Organ *(Breast, thyroid,testicle)*	N	N	N		N	Notes1, 2, 3	Notes 5, 6, 8, 10, 11, 12, 13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Musculo-skel. (Superficial)	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Notes 1 ,2, 3	Notes 5, 6, 8, 10, 12, 13
	Cerebral Vascular	N	N	N		N	Notes 1, 2, 3	Notes 5, 6, 8, 10, 12, 13

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: Boris Platform Ultrasound System
Transducer: L15-7 i.o. / 15 – 7.0 MHz / 38mm / Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative *(Spine, Vascular)*	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast)	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Notes 1,3	Notes 5, 8, 10, 12, 13
	Musculo-skel. (Superficial)	N	N	N		N	Notes 1,3	Notes 5, 8, 10, 12 ,13
	Intra-luminal							
	Other							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Coronary Artery)*							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Notes 1, 3	Notes 5, 8, 10, 12, 13
	Other							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **L17-5 / 5.0-17.0 MHz /39 -mm Linear Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 3	Notes 5, 6, 8, 10, 12, 13
	Abdominal	N	N	N		N	Notes 1,3	Notes 5, 6, 7, 8, 10, 12, 13
	Intra-operative *(Abdominal, vascular)*	N	N	N		N	Notes 1,3	Notes 5, 6, 8, 10, 12, 13
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Notes 1,3	Notes 5, 6, 8, 10, 12, 13
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Notes 1,3	Notes 5, 6, 8, 10, 12, 13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Notes 1,3	Notes 5, 6, 8, 10, 12, 13
	Musculo-skel. (Superficial)	N	N	N		N	Notes 1,3	Notes 5, 6, 8, 10, 12, 13
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1,3	Note 5, 6 ,8, 10, 12, 13
	Cerebral Vascular	N	N	N		N	Note 1,3	Note 5, 6 ,8, 10, 12, 13

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging Includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **S3-1 / 1.0-3.0 MHz /Phased Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	Notes 1, 3, 4	Notes 10, 13
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult	N	N	N	N	N	Notes 1, 2, 3, 4	Notes 10, 13
	Cardiac Pediatric	N	N	N	N	N	Notes 1, 2, 3, 4	Notes 10, 11, 13
	Trans-esophageal (Cardiac)							
	Fetal Echo	N	N	N	N	N	Notes 1, 2, 3, 4	Notes 10, 13
Peripheral Vessel	Peripheral vessel							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **S4-1 / 4.0 – 1.0 MHz / Phased Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 2, 3	Notes 10, 12, 13
	Abdominal	N	N	N		N	Notes 1, 3	Notes 10, 11, 12, 13
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel							
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **S6-2t Trans-Esophageal (Adult) 2.0-6.0 MHz/ 9 mm/ motorized phased**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N	N	N	Notes 1, 2, 3, 4	Note 10
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel							
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging Includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number k030455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **X-Matrix Multi-Dimensional Phased Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 2, 3	Notes 10, 12, 13
	Abdominal	N	N	N		N	Notes 1, 3	Notes 10, 11, 12, 13
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other *(Specify)*							
Peripheral Vessel	Peripheral vessel							
	Other *(Specify)*							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080455

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:
System: **Boris Platform Ultrasound System**
Transducer: **3D IVT /7.5 MHz /11.5 mm Motorized Linear Array**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Notes 1, 3	Notes 5, 10, 12, 13
	Abdominal	N	N	N		N	Notes 1,3	Notes 5, 10, 12, 13
	Intra-operative							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Fetal Echo	N	N	N		N	Notes 1, 2, 3	Note 12
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared; E= added under Appendix E
Additional Comments:
*Color Doppler includes Color Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;
Note 2: Combined modes include: B+M+Color
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD
Note 5: SonoCT
Note 6: Imaging for guidance of biopsy
Note 7: Infertility monitoring of follicle development
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging
Note 9: EFOV including Amplitude Doppler (N)
Note 10: Harmonic Imaging
Note 11: Contrast Imaging
Note 12: 3D Imaging
Note 13: XRES

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030455